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George Frey

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EXAMINER

SCHILLINGER, ANN M

ART UNIT

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3774

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/720,656	<b>Applicant(s)</b> FREY ET AL.	
	<b>Examiner</b> ANN SCHILLINGER	<b>Art Unit</b> 3774	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 17,22,23,26-31,34,37 and 58-77 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17,22,23,26-31,34,37 and 58-77 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 22, 23, 26, 34, 37, and 66-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Barlow et al. (US Pat. No. 2,623,517). Barlow et al. discloses the following of claim 17: a surgical instrumentation system comprising: a frame (10) including multiple portions lying in at least one plane; wherein said frame includes a first portion lying in a first plane (upper portion of the device shown in Fig. 1) and a second portion lying in a second plane (lower portion of the device shown in Fig. 1) that is transversely oriented to the first plane; and a plurality of retractors (I1 to I6) attachable to said frame portions (Figs. 1), each of said retractors including a blade portion (21, 28) extending transversely to said at least one plane when attached thereto, said blade portion including a tissue contacting surface (posterior surface of 21, 28) adapted to contact and retract tissue from the surgical approach; wherein one or more of said retractors is attachable to said first portion and one or more of said retractors is attachable to said second portion (Fig. 1); at least one adjustment mechanism (18) engageable with at least one of said retractors wherein said at least one adjustment mechanism includes a shaft (40) within a securement device (42) pivotally coupled with at least one of said retractors at a pivoting coupling location (located in Fig. 4, near element 37) adjacent a proximal end of said at least one of said retractors (Figs. 1 and 4) said pivoting coupling location toward said frame portions and

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said securement device movable along said frame portions, the securement device operable to engage said adjustment mechanism to said frame portion (col. 4, lines 1-45).

Barlow et al. discloses the following of claim 22: the system of claim 17, wherein said adjustment mechanisms each including a first condition in locking engagement with said respective frame portion to fixedly secure said adjustment mechanism relative to said frame portions (col. 3, lines 40-65), said adjustment mechanisms further each including a second condition in which at least one of said retractor is in pivotal engagement with said respective adjustment mechanism to permit said retractor to pivot relative to said frame (col. 1, line 49 through col. 2, line 20).

Barlow et al. discloses the following of claim 23: the system of claim 22 further comprising clamping devices (28, 32) mounted to said frame portions and releasably engagable to respective ones of said adjustment mechanisms.

Barlow et al. discloses the following of claim 26: the system of claim 22, wherein said adjustment mechanisms each include: an adjustment handle (47); a shaft assembly (left-side assembly of Fig. 4) extending from said adjustment handle and including said shaft and an engagement member (44) at an end of said shaft assembly opposite said adjustment handle (Fig. 4).

Barlow et al. discloses the following of claim 34: the system of claim 17 wherein at least one of said retractors include a first side defining a tissue contacting surface (posterior surface of 28) and an opposite second side configured to accommodate and support surgical instruments positioned therealong.

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Barlow et al. discloses the following of claim 37: the system of claim 17, wherein at least one said retractors include a blade portion defining a substantially flat tissue contacting surface (posterior surface of element 28) extending along a longitudinal axis of said blade portion, and at least another of said retractors include a blade portion defining a concave tissue contacting surface extending along a longitudinal axis of said at least another said retractor (posterior surface of element 21).

Barlow et al. discloses the following of claim 66: the system of claim 17, wherein in an operative position includes a medial portion adapted to lie along the posterior side of the spine, a caudal portion proximate one end of the medial portion and a cephalad portion proximate a second end of the medial portion (Fig. 1).

Barlow et al. discloses the following of claim 67: the system of claim 66, wherein in said operative position at least one of said plurality of retractors is attachable to said medial portion and is positionable adjacent the spinal mid-line, least one of said plurality of retractors is attachable to said caudal portion and is positionable in a caudal orientation relative to the spine, and least one of said plurality of retractors is attachable to said cephalad portion and is positionable in a cephalad orientation relative to the spine (Fig. 1).

Barlow et al. discloses the following of claim 68: the system of claim 17, further comprising one or more brackets (19) coupled to at least one frame portion configured to attach to a surgical table securing arm to support the system.

Claims 17, 22, 23, 26-31, 34, 37, and 58-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Gauthier (US Pat. No. 3,695,890). Gauthier discloses the following of the claims 17 and 37: a surgical instrumentation system comprising: a frame (F) including multiple

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portions lying in at least one plane; wherein said frame includes a first portion lying in a first plane (upper portion of the device shown in Fig. 1) and a second portion lying in a second plane (lower portion of the device shown in Fig. 1) that is transversely oriented to the first plane; and a plurality of retractors (A, A', B, B') attachable to said frame portions (Figs. 1-2); wherein one or more of said retractors is attachable to said first portion and one or more of said retractors is attachable to said second portion (Fig. 1); each of said retractors including a blade portion (B, B') extending transversely to said at least one plane when attached thereto, said blade portion including a tissue contacting surface (posterior surface of B, B') and an opposite second side (superior surface); at least one adjustment mechanism (Figs. 7, 15) engageable with at least one of said retractors wherein said at least one adjustment mechanism includes a shaft (68) within a securement device (10) pivotally coupled with said retractors at a pivoting coupling location adjacent a proximal end of said at least one of said retractors (Fig. 1a) said pivoting coupling location toward said frame portions and said securement device movable along said frame portions, the securement device operable to engage said adjustment mechanism to said frame portion (col. 4, lines 6-36).

Gauthier discloses the following of claim 22: the system of claim 17, wherein said adjustment mechanisms each including a first condition in locking engagement with said respective frame portion to fixedly secure said adjustment mechanism relative to said frame portions, said adjustment mechanisms further each including a second condition in which at least one of said retractor is in pivotal engagement with said respective adjustment mechanism to permit said retractor to pivot relative to said frame (col. 1, lines 34-47; col. 5, line 65 through col. 6, line 20).

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Gauthier discloses the following of claim 23: the system of claim 22 further comprising clamping devices (11) mounted to said frame portions and releasably engagable to respective ones of said adjustment mechanisms.

Gauthier discloses the following of claim 26: the system of claim 22, wherein said adjustment mechanisms each include: an adjustment handle (10, 68); a shaft assembly (Fig. 15) extending from said adjustment handle and including said shaft and an engagement member (11, 13) at an end of said shaft assembly opposite said adjustment handle (Fig. 4).

Gauthier discloses the following of claim 27: the system of claim 26, wherein said engagement member includes a number of teeth (12) configured to selectively interdigitate and lockingly engage a number of teeth (on elements 13) provided adjacent a proximal end of said retractor, said number of teeth engaging one another along concave-convex pivot path of said retractor (Fig. 16).

Gauthier discloses the following of claim 28: the system of claim 27, wherein said shaft assembly includes an outer shaft (M) and an inner shaft (A) movably positioned within said outer shaft, said engagement member extending from a distal end of said inner shaft.

Gauthier discloses the following of claim 29: the system of claim 28, wherein said adjustment handle is linked with said inner shaft, said adjustment handle being rotatable to non-rotatably and linearly advance said inner shaft and said engagement member between said first condition and said second condition (col. 6, lines 47-66).

Gauthier discloses the following of claim 30: the system of claim 27, wherein said adjustment mechanism includes a pair of plates (M) at a distal end thereof, and each of said

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retractor includes a pair of proximal flanges (54, at the location of label B') pivotally coupled to said pair of plates (Fig. 17).

Gauthier discloses the following of claim 31: the system of claim 30, wherein: each flange of said pair of proximal flanges includes an arcuate slot (where element 49 passes through) defining a pivot path of the respective said retractor; said engagement member includes a slot (where element A passes through) extending along a longitudinal axis of said shaft assembly; and said adjustment mechanism further comprises a roller pin (61).

Gauthier discloses the following of claim 34: the system of claim 17 wherein at least one of said retractors include a first side defining a tissue contacting surface (posterior surface of 28) and an opposite second side configured to accommodate and support surgical instruments positioned therealong.

Gauthier discloses the following of claim 58: a surgical instrumentation system to provide a surgical approach to a patient's spine, comprising: a frame (F) including multiple portions lying in at least one plane; a plurality of retractors (A, A', B, B') attachable to said frame portions, each of said retractors including a blade portion (B, B') extending transversely to said at least one plane, said blade portion including a tissue contacting surface (posterior surface of elements B, B') adapted to contact and retract tissue from the surgical approach; and at least one adjustment mechanism (Figs. 7, 15) coupled to respective ones of said plurality of retractors; said adjustment mechanisms each including a first condition in locking engagement with said respective adjustment mechanism, said adjustment mechanisms further each including a second condition in which at least one of said retractor is in pivotal engagement with said respective adjustment mechanism to permit said retractor to pivot relative to said frame (col. 1, lines 34-47;



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col. 5, line 65 through col. 6, line 20) wherein said adjustment mechanisms each include: an engagement member (F, 13) at a distal end thereof including a number of teeth (12) configured to selectively interdigitate and lockingly engage a number of teeth (on elements 13) provided adjacent a proximal end of said retractor, said number of teeth engaging one another along concave-convex pivot path of said retractor; and a pair of plates (at the location of label B', 54) at said distal end of said adjustment mechanism and said retractor includes a pair of proximal flanges (58) pivotally coupled to said pair of plates.

Gauthier discloses the following of claim 59: the system of claim 58, wherein each flange of said pair of proximal flanges includes an arcuate slot (where element 49 passes through) defining a pivot path of the respective said retractor; said engagement member includes a slot (where element A passes through) extending along a longitudinal axis; and said adjustment mechanism further comprises a roller pin (61).

Gauthier discloses the following of claim 60: the system of claim 58, further comprising another of said plurality of retractors attachable to said frame portion generally opposite said retractor (Fig. 1).

Gauthier discloses the following of claim 61: the system of claim 58, wherein at least one of said retractors include a blade portion defining a substantially flat tissue contacting surface (at the upper portion of element B') extending along a longitudinal axis of said blade portion, and at least another of said retractors includes a blade portion defining a concave tissue contacting surface extending along a longitudinal axis of said at least another retractor (at the lower portion of element B').

Gauthier discloses claims 62-67 as shown in Figure 1.

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Gauthier discloses the brackets of claim 68 in element 58.

Gauthier discloses the following of claim 69: the system of claim 58, wherein in an operative position said includes a medial portion adapted, a caudal portion, and a cephalad portion proximate a second end of the medial portion (Fig. 1).

Gauthier discloses the following of claim 70: the system of claim 69, wherein in said operative position at least one of said plurality of retractors is attachable to said medial portion and is positionable adjacent the spinal mid-line, least one of said plurality of retractors is attachable to said caudal portion and is positionable in a caudal orientation relative to the spine, and least one of said plurality of retractors is attachable to said cephalad portion and is positionable in a cephalad orientation relative to the spine (Fig. 1).

Gauthier discloses the following of claim 71: the system of claim 58, further comprising one or more brackets (M) coupled to at least one frame portion configured to attach to a surgical table securing arm to support the system.

Gauthier discloses the following of claim 72: a surgical instrumentation system to provide a surgical approach to a patient's spine, comprising: a frame (F) including a first portion (left side of frame) and a second portion (right side of frame); a plurality of retractors (A, A', B, B') secured to the frame and adapted to pivot relative to the frame, at least one of said retractors being secured to said first portion of said frame and extending transversely to said first portion (Fig. 1) and at least one other of said retractors being secured to said second portion of said frame and extending transversely to said second portion (Fig. 1); and an adjustment mechanism (Fig. 7, 15) for facilitating pivotal adjustment of the retractors; wherein said retractors are secured to the frame with securement devices (11, 13) each including a receptacle being

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slideable along a respective one of said first and second portions of said frame (col. 4, lines 28-36); and wherein each of said retractors is lockable in a selectable pivoting location by engagement of the adjustment mechanism with a portion of the retractor (col. 1, lines 34-47; col. 5, line 65 through col. 6, line 20).

Gauthier discloses the following of claim 73: the system of claim 72, wherein said frame further comprises a third portion (central portion), at least one of said retractors being secured to said third portion of said frame and extending transversely to said third portion (Fig. 1).

Gauthier discloses the following of claim 74: the system of claim 72, wherein at least one of said plurality of retractors include a blade portion defining a substantially flat tissue contacting surface (upper portion of element B') extending along a longitudinal axis of said blade portion, and at least another of said plurality of retractors includes a blade portion defining a concave tissue contacting surface extending along a longitudinal axis of said at least another retractor (lower portion of element B').

Gauthier discloses the following of claim 75: the system of claim 72, wherein at least one of said plurality of retractors include a first side defining a tissue contacting surface (posterior side of elements B, B') and an opposite second side configured to accommodate and support surgical instruments positioned therealong.

Gauthier discloses the following of claim 76: the system of claim 72, wherein at least one of said plurality of retractors include a tissue contacting surface (posterior side of elements B, B') adapted to contact and retract tissue from the surgical approach.

Gauthier discloses the following of claim 77: the system of claim 72, further comprising one or more brackets (58) coupled to at least one frame portion

### **Response to Arguments**

Applicant's arguments with respect to claim 71 have been considered but are moot in view of the application of the reference.

Applicant's remaining arguments filed 6/11/2010 have been fully considered but they are not persuasive. The Applicant contends that Barlow's head (18) is not an adjustment mechanism, as required by claim 17. The examiner respectfully disagrees. Element 18 is the head of the handle as shown in Figure 1. The handle serves an adjustment mechanism because it can be used by the user to move the retractors around the frame.

The Applicant also contends that the Barlow and the Gauthier references do not disclose the frame having two portions lying in two separate planes. The examiner respectfully disagrees. The upper and lower portions of the frames for both references lie within two transversely oriented planes that run from left to right, containing the upper and the lower portions. These two planes will be oriented transversely to one another.

Claim 34 states that the retractor has a tissue contacting surface on one side and an opposite side configured to accommodate and support surgical instruments. "Configured to/for" is functional language that is only considered to the extent in which it further limits the physical characteristics of the claimed device. The retractors of Barlow and Gauthier would be fully capable of accommodating and supporting any surgical instruments that come into contact with them. Likewise for claim 68, the device of Barlow would be fully capable of attaching to a surgical table.

The Applicant also states that Barlow and Gauthier do not disclose the retractors having a caudal, a cephalad, and a medial portion. The examiner respectfully disagrees. The examiner is

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interpreting the caudal, the cephalad, and the medial portions, to be the back, the front, and the middle portions, respectively, of the retractor. Please see Figures 1, 4, and 7 of Barlow and Figure 1 of Gauthier for illustrations of these portions of the retractors.

The Applicant further contends that element “M” of the Gauthier reference cannot be shown as a shaft in claim 28 and a plate in claim 30. The examiner respectfully disagrees. Claims 28 and 30 are dependent on claim 27. Because claim 30 is not dependent on claim 28, the element “M” may be interpreted as different elements for the different limitations that the dependent claims attach to claim 27. This same concept may be applied to Applicant’s arguments regarding claims 58, 68, and 77.

The Applicant argues that Gauthier's lever (element 54) may not be interpreted to be a flange. The examiner respectfully disagrees. Claims in a pending application must be given their broadest, reasonable interpretation. "Flange" is interpreted as "a projecting rim or edge" (flange. Dictionary.com. The American Heritage® Stedman's Medical Dictionary. Houghton Mifflin Company. <http://dictionary.reference.com/browse/flange> (accessed: February 23, 2011).) In view of this interpretation, it is maintained that element 54 of Gauthier may be read as a flange on the claim.

The Applicant states that Gauthier does not disclose the frame having a first portion and a second portion because Gauthier is a one-piece frame. The examiner respectfully disagrees. The term “portion” does not inherently mean that the frame must have separate and distinct pieces. A portion may simply be an area on the frame (i.e., the upper portion, lower portion, etc.). Therefore, it is maintained that Gauthier still reads on the claims.

### **Conclusion**

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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